Findings From an Informed Consent Audit

Deb Grady
Quality Management Coordinator
Office of Education and Compliance, CCR



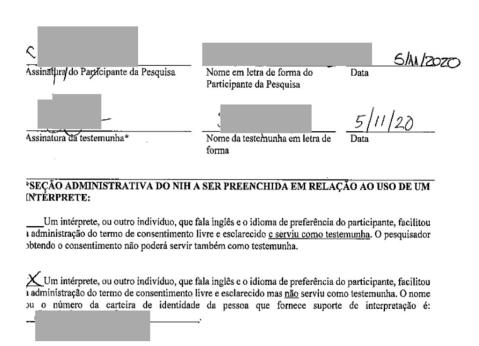
O1-C-0129
Eligibility Screening for the NIH Intramural Research Program Clinical Protocols

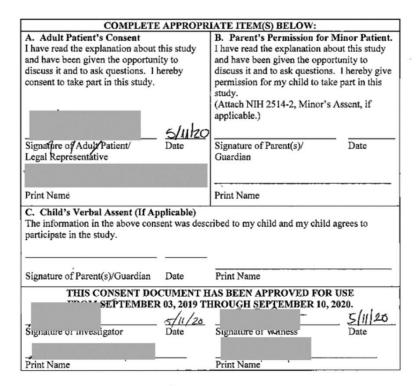
Overall Results

- Enrollment of non-English-speaking participants
 January through July 2020
 - Exclude April enrollments previously reviewed
- 37 informed consent documents and processes reviewed
- 3 had issues that required expeditated reporting to the IRB
- 24 had other issues
- 10 without problems

Reportable Issue 1

Adult Portuguese-speaking patient





Reportable Issue 1 Correct Process

- Signatures required for short form process:
 - On short form: patient and witness
 - On English long form: investigator obtaining consent and witness
 - If embedded questions, investigator asks question, then initials patient's response using the <u>investigator's</u> initials AND document in CRIS

**Non-English-speaking participants must NOT sign the English consent

Reportable Issue 2

 Finding: Investigator not listed on Key Study Personnel form

Reportable Issue 2 Correct Process

 Ensure that investigator obtaining consent is listed on the KSP form

AND

- Investigator has been assigned the role of obtaining consent
- Also, investigator must be delegated to obtain consent on Delegation of Tasks log

Reportable Issue 3

Adult Spanish-speaking patient, translated long form used

DILIGENCIE LA(S) CA	ASILLA(S) CORE	ESPONDIENTE(S) A CONTINUAC	IÓN:	
A. Consentimiento del paciente adulto		B. Autorización de los padres para un pacie		
		menor de edad	•	
He leído la explicación sobre este estudio, y se me ha		He leído la explicación sobre este estudio, y se me		
dado la oportunidad de hablar y hacer preguntas al		dado la oportunidad de hablar y hacer preguntas		
respecto. Por el presente, doy mi consentimiento para		respecto. Por el presente, doy mi consentimiento p		
participar en este estudio.		que mi hijo participe en este estudio.		
		(Anexar NIH 2514-2, Asentimiento	del menor,	
		corresponde.)		
	07/31/20			
	07/01/20			
Firma del paciente adulto	Fecha	Firma de los padres o tutores	Fecha	
o representante legal	recha	Tima de los padres o tutores	Геспа	
- representative regar				
Nombre en letra imprenta		Nombre en letra imprenta		
C. Asentimiento verbal del niño (s	i corresponde)			
A mi hijo se le explicó la información	n del consentimient	o anterior y acepta participar en este est	udio.	
Firma de los padres o tutores	Fecha	Nombre en letra imprenta		
		MIENTO SE APROBÓ PARA SU US HASTA EL 10 DE SEPTIEMBRE DI		
Firma del investigador	Fecha	Firma del testigo	Fecha	
Nombre en letra imprenta		Nombre en letra imprenta		

MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY Adult Patient or Parent, for Minor Patient			
STUDY NUMBER: 01-C-0129	CONTINUATION: page 12 of 12 pages			
COMP	LETE APPROP	RIATE ITEM(S) BELOW:		
A. Adult Patient's Conser		B. Parent's Permission fo	r Minor Patient	
I have read the explanation about this study		I have read the explanation about this study		
and have been given the opportunity to		and have been given the opportunity to		
discuss it and to ask questions. I hereby		discuss it and to ask questions. I hereby give		
consent to take part in this s	tudy.	permission for my child to take part in this		
		study.		
		(Attach NIH 2514-2, Minor applicable.)	's Assent, if	
Signature of Adult Patient/	Date	Signature of Parent(s)/	Date	
Legal Representative		Guardian		
Print Name		Print Name		
C. Child's Verbal Assent	(If Applicable)			
		cribed to my child and my chi	ld agrees to	
Signature of Parent(s)/Guar	dian Date	Print Name		
The second secon		HAS BEEN APPROVED FO THROUGH SEPTEMBER 10		
Signature of Investigator	Date	Signature of Witness	Date	
Print Name		Print Name		
Finit Parise		Fint Name		

Reportable Issue 3 Correct Process

- When using a translated long form, investigator signs the translated long form
 - No one signs the English form
- Certificate of translation in regulatory file

Other Issue 1

MEDICAL RECORD

CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY
CHINESE (SIMPLIFIED) – PRE-REVISED COMMON RULE

机构/中心:

首席研究员:

研究项目编号:

研究项目名称:

研究小组邀请您参与研究。

研究参与与否全凭自愿,如果您拒绝参与或决定终止参与,您不会受到惩罚或损失利益。 研究小组向您提交综述后,还会提供研究相关的更多详细资料,其中必须包括:

- 1) 研究的目的、程序和时限;
- 2) 任何实验性程序:



Other Issue 1 Correct Process . . .

- Complete the blank sections of short form word document so information can be typed in:
 - Header protocol information on page 1

MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY	
	ENGLISH – COMMON RULE	
	FOR STUDIES INITIALLY APPROVED ON OR PRIOR TO 1/21/2019	

INSTITUTE/CENTER:
PRINCIPAL INVESTIGATOR:
STUDY NUMBER:
STUDY TITLE:

You are being asked to participate in a research study.

... Other Issue 1 Correct Process

Contact information on page 2

	CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY
	ENGLISH – COMMON RULE
	FOR STUDIES INITIALLY APPROVED ON OR PRIOR TO 1/21/2019
esearch.	at (phone number) any time you have questions about the

Other Issue 2

- Adult Spanish-speaking patient
- Consent process via telephone

Protocol Identification:

Consent Obtained By: XXXX

Consent Version: U

Date/Time Of Consent: 02/03/2020 09:00

Protocol Selector: Please see below for associated protocol.

Protocol Title: 2001-C-0129; Eligibility Screening and Tissue Procurement for the NIH Intramural

Research Program Clinical Protocols: PI: Caryn Steakley, R.N.

Consent Type:

How Was Consent Conducted: Telephone consent and Use of interpretor (including staff or other

parties)

Date Of Signed Consent By The Investigator: 02/03/2020

Name Or ID Number Of Interpretor: XXXX Language Used By Interpretor: Spanish

Consent Process:

A Copy Of The Consent Was Given To The Participant To Review Prior To Signing: Yes



Comments:

Patient agreed on the phone on 2/3/2020 to participate in the study. Paperwork was returned on 2/5/2020. Paperwork was dated and witnessed on 2/3/2020. Consent was valid on date of phone conversation.



Other Issue 2 Correct Process

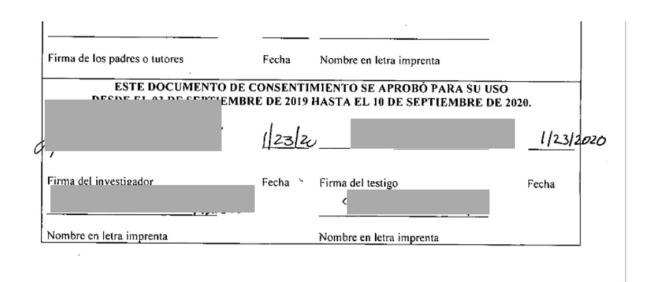
- Telephone consent process
 - Date of consent is the date the patient agrees to participate – usually date of telephone call
 - Patient should sign and date consent for the date he/she agreed to participate
 - Investigator obtaining consent signs and dates consent, using the date the signed consent was received by the investigator
- CRIS documentation write note within 24 hours of telephone conversation
 - Addend note when signed consent is returned

Short Form Consent Process via Telephone

- Must use witness (witness should be at NIH, not with patient)
 - Date of consent is the date the patient agrees to participate – usually date of telephone call
 - Patient should sign and date consent the short form only using the date he/she agreed to participate
 - Investigator and witness sign and date the long form consent using the date of consent
 - Witness signs and dates short form consent, using the date the signed consent was received by the investigator

Other Issue 3

 Adult Spanish-speaking patient, translated long form which patient signed

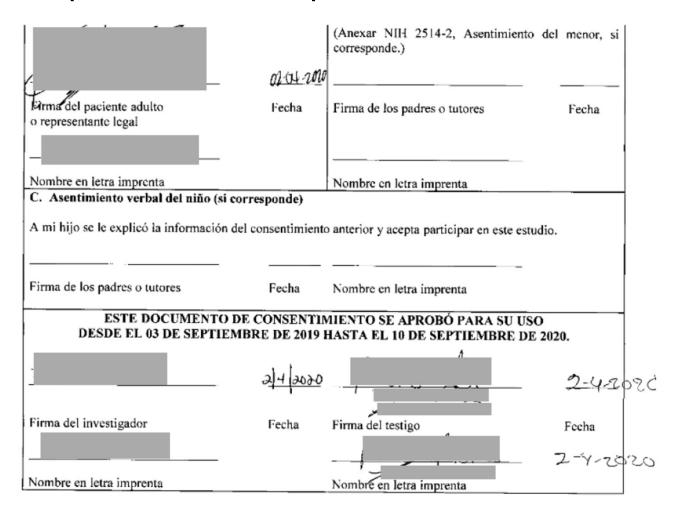


Other Issue 3 Correct Process

- Witness is NOT needed when using the translated long form consent
- Witness only required for short form process

Other Issue 4

- Adult Spanish-speaking patient, translated long form
- Consent process via telephone





Other Issue 4 Correct Process

- If consent is obtained via telephone and the consent is returned with a witness signature, please explain in note that consent was returned with a witness signature and the short form process was not used for the consent process
- Witness only required for short form process

Other Issue 5

Adult Spanish-speaking patient, translated long form

Protocol Identification:

Consent Obtained By: XXXX

Consent Version: U

Date/Time Of Consent: 02/12/2020 14:30

Protocol Selector: Please see below for associated protocol.

Protocol Title: 2001-C-0129: Eligibility Screening and Tissue Procurement for the NIH Intramural

Research Program Clinical Protocols: PI: Caryn Steakley, R.N.

Consent Type:

How Was Consent Conducted: Telephone consent and Use of interpretor (including staff or other

parties)

Date Of Signed Consent By The Investigator: 02/03/2020

Name Or ID Number Of Interpretor: XXXXX

Language Used By Interpretor: Spanish

Comments:

Patient agreed on the phone on 2/3/2020 to participate on the study. Paperwork was returned on 2/11/2020. Patient returned the blood work on 2/4/2020 but forgot to send protocol consent. Consent version "U" was valid on date of phone conversation.

Other Issue 5 Correct Process

- Review note to ensure information is correct
- Date of consent is the date the patient agrees to participate in the study – usually the date of the telephone conversation
- If there are discrepancies in dates, please explain in note

Other Issue 6

CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY MEDICAL RECORD KOREAN -- REVISED COMMON RULE FOR STUDIES INITIALLY APPROVED AFTER 1/21/2019

기관/센터:

National Concer Institute

연구책임자: 0/-C-0129

연구번호: Caryn STeakley LN

연구제목: Bligibility Screening and Tissue Procure montfor the NIH Intramural Research Program Clinical Protecols

귀하께서는 본 연구에 참여해 주실 것을 요청 받으셨습니다. 이 연구 참여에 동의하시기 전에 조사 연구 요약을 받으셔야 합니다. 이 요약에는 귀하가 연구에 참여 또는 참여하지 않을 이유를 이해하는 데 주요 정보가 포함되어야 합니다.

Other Issue 6 Correct Process . . .

 If the study was initially approved prior to or on 01/21/2019, use the Common Rule short form

MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY
	ENGLISH – COMMON RULE
	FOR STUDIES INITIALLY APPROVED ON OR PRIOR TO 1/21/2019

INSTITUTE/CENTER:

PRINCIPAL INVESTIGATOR:

STUDY NUMBER:

STUDY TITLE:

You are being asked to participate in a research study.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you

... Other Issue 6 Correct Process

 If the study was initially approved after 01/21/2019, use the Revised Common short form

MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY	
	ENGLISH – REVISED COMMON RULE	
	FOR STUDIES INITIALLY APPROVED AFTER 1/21/2019	

INSTITUTE/CENTER:

PRINCIPAL INVESTIGATOR:

STUDY NUMBER:

STUDY TITLE:

You are being asked to participate in a research study. Before you agree, you must first be provided with a summary of the research study. This summary must contain the key information to help you understand the reasons why you might or might not want to join the study.

Other Issue 7

Adult Spanish-speaking patient, translated long form

Protocol Identification:

Consent Obtained By: XXXX

Consent Version: V

Date/Time Of Consent: 07/30/2020

Protocol Selector: Please see below for associated protocol.

Protocol Title: 2001-C-0129 ; Eligibility Screening and Tissue Procurement for the NIH Intramural

Research Program Clinical Protocols: PI: Caryn Steakley, R.N.

Consent Process:

A Copy Of The Consent Was Given To The Participant To Review Prior To Signing: Yes

The Protocol Was Discussed With The Participant In a Private Setting: Yes

The Participant Verbalized Understanding Of The Protocol Study Procedure, Reasonably

Foreseeable Risks And Discomforts, Benefits, Disclosure Of Alternative

Procedures/Treatments, Confidentiality Of Record, Compensation And Treatment For Injury,

Contact Information, And That Participation Is Voluntary: Yes

Questions Were Answered And Addressed Prior To Consent: Yes

Consent Was Obtained Before Any Study Procedures/Tests Were Performed: Yes

A Copy Of The Consent, Signed And Dated By The Investigator And Participant, Was Given To

The Participant: Yes

The Original Signed And Dated Consent Was Sent To The Health Information Management

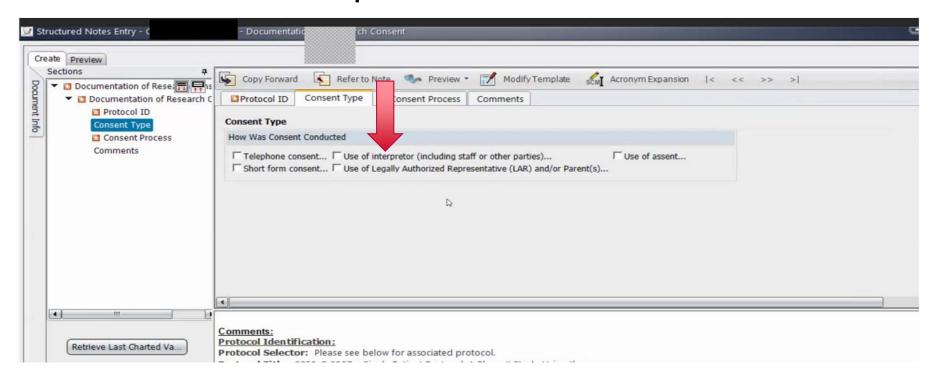
Department: Yes

Electronic Signatures:



Other Issue 7 Correct Process

 Select all applicable "consent types" used in the informed consent process



What do you do?

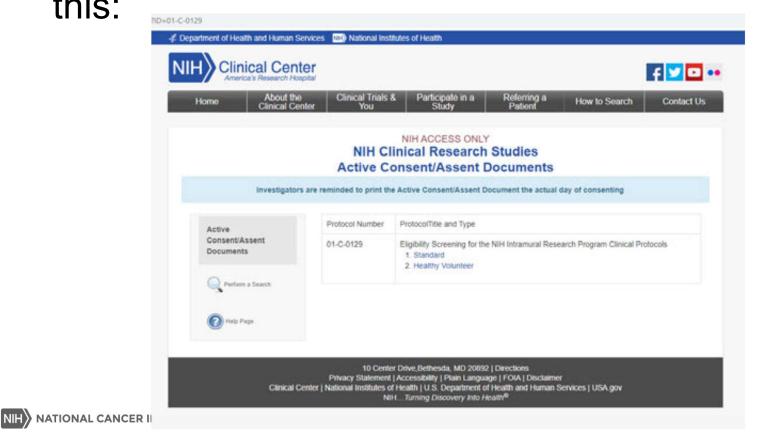
- You have a Spanish-speaking patient you want to enroll onto the screening protocol
- You go to the informed consent website and see

What do you do?

You have a Spanish-speaking patient you want to enroll onto the screening protocol

You go to the informed consent website and see

this:



Correct Process

- If the Spanish translated long form is not available on the consent website, you must use the Spanish short form and the short form consent process
 - Need a witness for the process
- Always pull the consent from the website do not save a version of the consent
- The screening protocol was recently amended and the revised English consents posted Sept 2 but translated long form not yet available

04-C-0165

Data Collection,

Standard Care and
Interventions in CCR,

NCI

Overall Results

- Enrollment of non-English-speaking participants and some minor participants January through July 2020
 - Exclude April enrollments previously reviewed
- 11 informed consent documents and processes reviewed
- 4 had issues that required expeditated reporting to the IRB
- 5 had other issues
- 2 without problems

Reportable Issue 4

Adult Amharic-speaking patient, short form process used

MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY AMHARIC – PRE REVISED COMMON RULE			
ይህን ምርምር በተ <i>ማ</i> ለከተ በማን	ኛውም ጊዜ ተያቁ ቢኖርዎ ለ <i>(ስም) በ(ስልክ ቀጥር) ማናገር</i> ይችላሉ።	MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN NIH CLINIC	CAL RESEARCH STUDY
ቢኖርዎ ለ <i>(ስም)</i> በ <i>(ስልከ</i>	ስለሚኖርዎ መብቶች ወይም ጉዳት ቢደርስብዎ ምን ማድረግ እንዳለብዎ በተመለከተ ተያቄ ን ቁጥር) ማናገር ይችላሉ። ምርምር ጥናቱ በተመለከተ፣ ከላይ ያለውን መረጃ ጭምር፣ በቃል መግለሜ እንደተሰጥዎና ተዋል ማለት ነው።	Witness to the oral short-f short-consent process and th translation. Witness:	orm consent process only: This section is only require its English consent form has been approved by the IRB	d if you are doing the oral for use as the basis of
		Signature of Witness*	Print Name of Witness	Date
የምርምር ተሳታፊ ፊርማ	マテ クリ / 17 / 2(12 C) 中ツ (サイン・イン・イン・イン・イン・イン・イン・イン・イン・イン・イン・イン・イン・イ	*NIH ADMINISTRATIV INTERPRETER:	E SECTION TO BE COMPLETED REGARDS	NG THE USE OF AN
የምስከር <i>ራርጣ</i> *	የምስክር ስም ይጻፉ ቀን			
the cours a company of the state of the stat	ተ በኢን አይ እ ች የአስተደየሮ ክፍለ መሞለት የለበት:			

Reportable Issue 4 Correct Process

- By regulations, the short for process must be witnessed and the witness must sign the short form and long form
- Witness must be identified in note

Reportable Issue 5...

- 16-year-old Spanish-speaking patient
 - Per protocol "Children under the age of 18, but who are age 12 or older will be asked to sign an age appropriate assent form."
- Translated long form not available so short form process used

YOU MAY STOP BEING IN THIS ANY TIME Firmar este documento significa que se le explicó verbalmente el estudio de investigación, incluida la Remember, being in this study is up to you and no one will be upset if you don't want to take part información anterior, y que acepta participar voluntariamente. in this study or even if you change your mind later and want to stop. However, because we have rules here at NIH about medical information, even if you leave the study, we will be able to use the information we've collected from you. It will not have your name on it though, or any other way to identify you. RE-CONSENTING Nombre en letra imprenta del Once you have turned 18, we will contact you to find out if you would still like to participate in participante de la investigación the study. Assent of Participant: Nombre en letra imprenta del Firma del testigo* *SECCIÓN ADMINISTRATIVA DE LOS NIH PARA COMPLETAR EN CASO DE USAR LOS Print Name of Participant Signature of Participant SERVICIOS DE UN INTÉRPRETE: Un interprete u otra persona que habla inglés y el idioma que prefiere el participante facilitó la Investigator: administración del consentimiento informado y sirvió de testigo. El investigador que obtiene el consentimiento no puede servir de testigo. Print Name of Investigator Signature of Investigator

... Reportable Issue 5

- 16-year-old Spanish-speaking patient
 - Per protocol "Children under the age of 18, but who are age 12 or older will be asked to sign an age appropriate assent form."

Protocol Identification:

Consent Obtained By: XXXX Consent Version: 10/31/2019

Date/Time Of Consent: 02/10/2020

Protocol Selector: Please see below for associated protocol.

Protocol Title: 2004-C-0165: Data Collection, Standard Care and Interventions for Oncology Patients

and Donors, CCR, NCI: PI: James L. Gulley, M.D.

Consent Process:

A Copy Of The Consent Was Given To The Participant To Review Prior To Signing: Yes

Comments:

a spanish interpreter was used. Pt is 16 yo minor. Parent signed the spanish short form. Pt also signed a assent form.

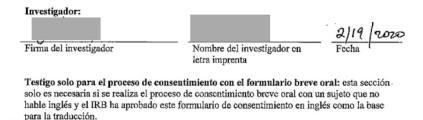


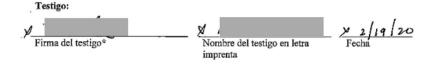
Reportable Issue 5 Correct Process

- If a protocol requires written assent and a translated assent form in the child's language is not available, obtain verbal assent using interpreter
 - Document verbal assent in CRIS note
- If the child speaks and understands English and the parents agree, he/she can sign the English assent form
 - Document in CRIS note that the child speaks and understands English so signed the English assent with the parents approval

Reportable Issue 6

 Adult Spanish-speaking patient who signed the translated long form





*SECCIÓN ADMINISTRATIVA DE LOS NIH QUE DEBERÁ DILIGENCIARSE RESPECTO AL USO DE UN INTÉRPRETE:

Un intérprete, u otra persona, que habla inglés y el idioma de preferencia del participante facilitó

la administración del consentimiento informado y actuó como testigo. El investigador que obtiene el consentimiento no puede actuar al mismo tiempo como testigo.

Un intérprete, u otra persona, que habla inglés y el idioma de preferencia del participante facilitó

la administración del consentimiento informado, pero <u>no</u> actuó como testigo. El nombre o el código de identificación de la persona que prestó los servicios de apoyo de interpretación es:

Protocol Identification:

Consent Obtained By: XXXX Consent Version: 10/31/2019

Date/Time Of Consent: 02/19/2020 09:30

Protocol Selector: Please see below for associated protocol.

Protocol Title: 2004-C-0165: Data Collection, Standard Care and Interventions for Oncology Patients

and Donors, CCR, NCI: Pl: James L. Gulley, M.D.

Consent Process:

A Copy Of The Consent Was Given To The Participant To Review Prior To Signing: Yes

The Protocol Was Discussed With The Participant In a Private Setting: Yes

The Participant Verbalized Understanding Of The Protocol Study Procedure, Reasonably

Foreseeable Risks And Discomforts, Benefits, Disclosure Of Alternative

Procedures/Treatments, Confidentiality Of Record, Compensation And Treatment For Injury,

Contact Information, And That Participation Is Voluntary: Yes

Questions Were Answered And Addressed Prior To Consent: Yes

Consent Was Obtained Before Any Study Procedures/Tests Were Performed: Yes

A Copy Of The Consent, Signed And Dated By The Investigator And Participant, Was Given To

The Participant: Yes

The Original Signed And Dated Consent Was Sent To The Health Information Management

Department: Yes



Reportable Issue 6 Correct Process

- ANY person who provides interpretation must be identified on the consent, NIH Administrative section AND in the CRIS note
- No witness needed for translated long form

*NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:
An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.
An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but <u>did not</u> serve as a witness. The name or ID code of the person providing interpretive support is:

Other Issue 8

- 10-year-old Spanish-speaking patient
 - Per protocol: "Verbal assent will be obtained as appropriate for all children under the age of 12 and 7 years or older."

Signature of Investigator

Translated long form not available so short form process used

Firma del participante de la investigación

Nombre en letra imprenta del participar del testigo*

Nombre en letra imprenta del participante del a investigación

Nombre en letra imprenta del Fecha

*SECCIÓN ADMINISTRATIVA DE LOS NIH PARA COMPLETAR EN CASO DE USAR LOS SERVICIOS DE UN INTÉRPRETE:

Un intérprete u otra persona que habla inglés y el idioma que prefiere el participante facilitó la administración del consentimiento informado y sirvió de testigo. El investigador que obtiene el consentimiento no puede servir de testigo.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date
χ	X	
Signature of Parent/Guardian (as applicable)	Print Name of Parent/Guardian	Date
Assent: (Use this section only when this proce requires a separate assent form for this popula	11 / /	ors. Do not use if an IRB
I have had this study explained to me in a way it, and I have had the chance to ask questions.		ne opportunity to discuss
Assent of Minor: (as applicable)		
	Print Name of Minor	1/28/2020
Signature of Minor	Print Name of Minor	Date
Investigator:		1/28/2020

Print Name of Investigator

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given

the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Date

Other Issue 8 . . .

- 10-year-old Spanish-speaking patient
 - Per protocol: "Verbal assent will be obtained as appropriate for all children under the age of 12 and 7 years or older."
- Translated long form not available so short form process used

información anterior, y que acepta participar voluntariamente.

Firma del participante de la investigación

Nombre en letra imprenta del participante de la investigación

Fecha

Firma del testigo*

Nombre en letra imprenta del testigo

Fecha

Fecha

*SECCIÓN ADMINISTRATIVA DE LOS NIH PARA COMPLETAR EN CASO DE USAR LOS SERVICIOS DE UN INTÉRPRETE;

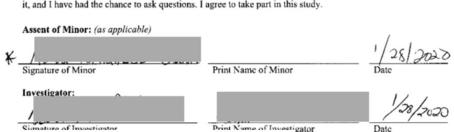
Un intérprete u otra persona que habla inglés y el idioma que prefiere el participante facilitó la administración del consentimiento informado y sirvió de testigo. El investigador que obtiene el consentimiento no puede servir de testigo.

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date	
χ	X		
Signature of Parent/Guardian (as applicable)	Print Name of Parent/Guardian	Date	

Assent: (Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.



Comments:

The patient and family were consented to the standard of care NCI study. Informed consent and assent to risks/benefits of treatment were explained to the patient and family and all questions were answered via a Spanish interpreter. The patient speaks English and signed the assent document as well.



... Other Issue 8

- 10-year-old Spanish-speaking patient
 - Per protocol: "Verbal assent will be obtained as appropriate for all children under the age of 12 and 7 years or older."

Consent Type:

How Was Consent Conducted: Short form consent, Use of interpretor (including staff or other parties), Use of Legally Authorized Representative (LAR) and/or Parent(s) and Use of assent

Was A Witness Present During The Short Form Consent Process?: Yes

Name Of Witness For For Short Form Consent: XXXX

Name Or ID Number Of Interpretor: XXXX Language Used By Interpretor: Spanish

Name Of Legally Authorized Representative (LAR): XXXX Is Participant A Minor Or Adult Unable To Consent?: Minor

Assent Type: Written

Assent Was Obtained Before Any Study Procedures/Tests Were Performed: Yes

A Copy Of The Assent Was Given To The Participant To Review Prior To Signing: Yes A Copy Of The Assent, Signed And Dated By the Investigator, And Was Given To The

Participant (If Written Assent Was Given): Yes

The Orginal Signed And Dated Assent Was Sent To The Health Information Management

Department: Yes



Other Issue 8 Correct Process

- The minor signing the informed consent document section "Assent of Minor" is NOT written assent
- Review CRIS note to ensure correct information

Other Issue 9

- 13-year-old English-speaking patient
 - Per protocol "Children under the age of 18, but who are age 12 or older will be asked to sign an age appropriate assent form."
 - Written assent form signed by patient

Consent Type:

How Was Consent Conducted: Use of assent

Is Participant A Minor Or Adult Unable To Consent?: Minor

Assent Type: Written

Assent Was Obtained Before Any Study Procedures/Tests Were Performed: Yes

A Copy Of The Assent Was Given To The Participant To Review Prior To Signing: Yes A Copy Of The Assent, Signed And Dated By the Investigator, And Was Given To The

Participant (If Written Assent Was Given): Yes

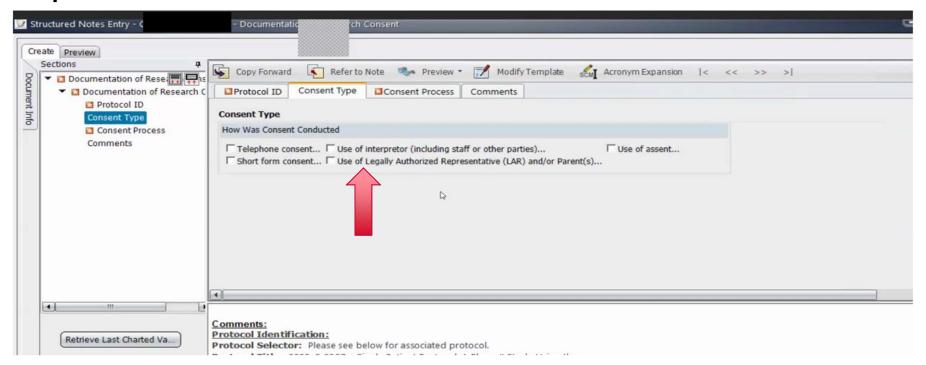
The Orginal Signed And Dated Assent Was Sent To The Health Information Management

Department: Yes



Other Issue 9 Correct Process

 Select all applicable "consent types" used in the informed consent process, including LAR and/or parents



Other Issue 10 . . .

- 11-year-old English-speaking patient
 - Per protocol: "Verbal assent will be obtained as appropriate for all children under the age of 12 and 7 years or older. . .
 The consent/assent process will be documented in the child's medical record."

Parent/Guardian of a Minor Participant: I the opportunity to discuss it and to ask question	have read the explanation about this stu- ns. I give permission for my child to tak	dy and have been given	Protocol Identification:
			Consent Obtained By: XXXX
Signature of Parent/Guardian	Francisanie of Farenti Opportunian	6-22-2020 Date	Consent Version: 4/15/20
			Date/Time Of Consent: 06/22/2020 13:05
Signature of Parent/Guardian (as applicable)	Print Name of Parent/Guardian	Date	Protocol Selector: Please see below for associated protocol.
			Protocol Title: 2004-C-0165: Data Collection, Standard Care and Interventions in CCR, NCI: Pl: Jame
Assent: (Use this section only when this proce- requires a separate assent form for this popula	ss is approved by an IRB for older minoi uton.)	rs. Do not use if an IRB	L. Gulley, M.D.
I have had this study explained to me in a way it, and I have had the chance to ask questions.		e opportunity to discuss	
the distribution of the character to ask questions.	agree to take part in this study.	, , ,	Consent Type:
Assent of Minor: (as applicable)			How Was Consent Conducted: Use of Legally Authorized Representative (LAR) and/or Parent(s)
			Name Of Legally Authorized Representative (LAR): XXXX
Signature of Minor	Print Name of Minor	Date	
Investigator			Consent Process:
,		6/22/20	A Copy Of The Consent Was Given To The Participant To Review Prior To Signing: Yes
Signature of Investigator	Print Name of Investigator	Date	



Other Issue 10 Correct Process

- Assent process must be documented in CRIS
 OR
- If the parents and/or investigator determine it is not appropriate to assent the child, this must be documented in CRIS

IMPORTANT

- If you do not routinely enroll non-English-speaking participants, PLEASE use your resources
 - Review NIH SOP 12: Requirements of Informed Consent
 - Review CCR SOP PM-2: Obtaining and Documenting the Informed Consent Process
 - Consult with team leads and/or the Office of Education and Compliance (Liz, Deb, Tracy and Armine!)
- If a non RNC investigator obtains informed consent, please review documents and CRIS note to ensure correct process and note
- DO NOT write a Documentation of Research Consent note in CRIS if you were not present for the consent process

QUESTIONS

